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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,665	09/10/2001	Adam J. Katz	30448.77USW1	9133

26941 7590 03/11/2003

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EXAMINER

SANDALS, WILLIAM O

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/936,665

Applicant(s)
Katz et al.

Examiner
William Sandals

Art Unit
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 30, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 139-146 is/are pending in the application.
- 4a) Of the above, claim(s) 5-7 and 144-146 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 139-143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 & 8
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 10
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Newly submitted claims 144-146 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 144-145 are drawn to a method of obtaining an adipose derived fraction enriched for multipotent cells. Claims 1-4 are drawn to an adipose derived stem cell. The inventions are distinct as a product and a process of making. The adipose derived stem cell of claims 1-4 may be obtained by a method other than the method of claims 144-146, such as culturing cells directly from a tissue sample, or by isolating the stem cells from the adipose tissue sample. Claim 146 is drawn to an adipose derived lattice which is devoid of cells. The lattice of claim 146 is distinct, and biologically and physically different from the cells of claims 1-4. Thus, the lattice of claim 146 is patentably distinct from the cells of claims 1-4.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 144-146 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendments

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2. Claims 1-7 and 1-146 are pending. Claims 1-4 have been amended in Paper No. 9, filed on December 30, 2002. Claims 139-146 are newly submitted in Paper No. 9. Claims 5-7 stand as non-examined. Claims 144-146 are withdrawn from consideration as drawn to a non-elected invention. Claims 1-4 and 139-143 are examined herewith.

3. Arguments regarding the rejections of the claims under 35 USC 102 over US 5,486,359, US 5,728,739, Ailhaud et al. (1983), Vassaux et al., Ailhaud et al. (1985), Marko et al., WO 98/04682, US 5,854,292, US 5,827,897 and US 5,827,740 in Paper No. 9 have been found convincing, and the rejections are withdrawn.

4. Arguments regarding the rejection of claims 1-4 under 35 USC 102 over Soda et al. in Paper No. 9 have not been found convincing. Response to arguments in Paper No. 9 are included in the rejection repeated below.

5. Amendments to the claims have overcome the rejection of claims 1-4 under 35 USC 101 and the rejection is withdrawn.

6. The language of claim 142 recites "[a] fraction of an adipose tissue sample from a subject". This language is understood to mean that the fraction of an adipose tissue sample is taken (emphasis added) from a subject, indicating that the fraction of an adipose tissue sample is isolated from the subject. Therefore, the language of the claim does not fall under the guidelines for a rejection under 35 USC 101.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

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Claim Objections

8. Claims 5-7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.
9. Claim 141 is objected to because of the following informalities: Claim 141 recites at line 1, "[t]he isolate adipose derived". This phrase contains a typographical error. The word "isolate" should read "isolated". Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 140-143 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to stem cells that can differentiate into ectodermal and endodermal phenotypes. There is no support in the originally filed claims or specification which reasonably describes the instant claimed stem cells which can differentiate into ectodermal and endodermal phenotypes. Paper No. 19 points to the specification at page 3,

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lines 14-19 for support for the language "can differentiate into ectodermal and endodermal phenotypes". No support is found at this location in the specification. Rather, general language is found which refers to specific developmental phenotypes such as adipogenic and chondrogenic. The inclusion of the terms ectodermal and endodermal phenotypes suggest the developmental capacity of the instant stem cell is a very primitive stem cell. No evidence is presented to support this conclusion, and no language is presented to support the assertion. The term "can differentiate into ectodermal and endodermal phenotypes" is therefore new matter.

12. Claims 140-143 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 140-143 are drawn to isolated stem cells which "can differentiate into mesodermal, ectodermal and endodermal phenotypes". The specification supports the claim to differentiation into the genus of mesodermal phenotypes, but fails to support any conclusion that the stem cells can differentiate into the genus of ectodermal or endodermal phenotypes. The genus of ectodermal or endodermal phenotypes is broad and indicates that the claimed stem cell is a very primitive type. Example 1 at pages 17-19 of the instant specification provides four species of mesodermal differentiation phenotypes, which is sufficient to support the claimed differentiation into the genus of mesodermal phenotypes. No examples of species of differentiation of the claimed stem cells into ectodermal or endodermal

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phenotypes are provided in the instant claims or specification. No structural or biological evidence has been provided to characterize the stem cells as a primitive type capable of differentiating into ectodermal or endodermal phenotypes. Thus, no written description has not been provided to support the language of claims 140-143 drawn to differentiation of the instant claimed stem cells into ectodermal or endodermal phenotypes.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Soda et al.

Soda et al. (see the entire article) teaches a mammalian adipose-derived stem cell substantially free of mature adipocytes which may be cultured to produce a homogeneous population of stem cells.

Response to Arguments

15. Arguments presented in Paper No. 9 assert at page 10, that Soda et al. does not teach each and every element of the claims. It is argued that Soda et al. does not teach that the stem cells are multipotent.

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Soda et al. teach the culturing of adipose derived stem cells. Soda et al. teach that the stem cell is pluripotent at page 82. The words multipotent and pluripotent have a meaning which is sufficiently close, such that the limitations of the claims are met. The reference therefore, teaches the limitations of claims 1-2.

Arguments presented in the interview summary of February 11, 2003 assert that Soda et al. is not enabled.

Soda et al. teach at the first paragraph of page 79 that stem cells exist in adipose tissue. At page 82, lines 9-14 and lines 34-36, Soda et al. teach that they have carefully considered whether the stem cells isolated from adipose tissue are committed, and thus not pluripotent. They conclude that the stem cells are in fact pluripotent. Therefore, the teachings of Soda et al. are enabled for isolation of a pluripotent stem cell from adipose tissue.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 1-4 and 139-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soda et al. in view of WO 98/04682 (Pittenger) and US 5,827,740 (Pittenger).

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The claims are drawn to an adipose-derived stem cell (multipotent cell) substantially free of mature adipocytes which may can differentiate into two or more developmental phenotypes to produce a homogeneous population of stem cells, where the cells can be cultured for at least 15 passages without differentiating. The cells may be from a human.

Soda et al. teach the invention as described above in the rejection under 35 USC 102. Soda et al. teach that the stem cells are pluripotent and may be induced to differentiate into adipocytes.

Soda et al. did not teach that the cells can be cultured for at least 15 passages without differentiating, nor that the cells may be from a human.

Pittenger (WO) teaches (see especially pages 3-4, example 1 and the claims) a mammalian (human) tissue-derived multipotent stem cell which may be cultured in DMEM + about 10% fetal bovine serum for at least 15 passages without differentiating, and which has two or more developmental phenotypes which may be human. Pittenger (WO) teaches that the stem cells may be induced to differentiate into adipocytes.

Pittenger (US) teaches (see especially columns 2, 3, 6, 7, 9 and the claims) a mammalian (human) tissue-derived multipotent stem cell which may be cultured in DMEM + about 10% fetal bovine serum for at least 15 passages without differentiating, and which has two or more developmental phenotypes which may be human. Pittenger (US) teaches that the stem cells may be induced to differentiate into adipocytes.

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It would have been prima facie obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Soda et al. with Pittenger (WO) and Pittenger (US) to produce the instant claimed invention because each of Soda et al., Pittenger (WO) and Pittenger (US) teach the isolation of multipotent stem cells from a tissue, where the isolated stem cells may be cultured and induced to differentiate into adipocytes. Pittenger (WO) and Pittenger (US) each make it obvious to modify the invention to culture the stem cells in DMEM + about 10% fetal bovine serum for at least 15 passages without differentiating, where the stem cells have two or more developmental phenotypes and where the stem cells may be human.

One of ordinary skill in the art would have been motivated to modify the teachings of Soda et al. with Pittenger (WO) and Pittenger (US) to produce the instant claimed invention because each of Pittenger (WO) and Pittenger (US) teach the desirable and beneficial isolation, culturing and differentiation of multipotent stem cells into multiple phenotypes, where the stem cells are isolated from a tissue. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Soda et al., Pittenger (WO) and Pittenger (US).

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.


Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.

Examiner

March 8, 2003


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